

CLIENT & SAMPLE INFORMATION

Client	N/A	Analysis Date	06/11/2026
Product Name	DSIP	Strength	10 mg
Lot / Batch	JA2026164	Condition	Lyophilized

This Certificate of Analysis certifies that the sample listed herein was tested for bacterial endotoxin using a kinetic chromogenic LAL assay in accordance with USP <85> Bacterial Endotoxins Test.

TEST METHODOLOGY

Test Performed	Quantitative Bacterial Endotoxin Test	Compendial Ref	USP <85>
Assay Type	Kinetic Turbidimetric	Detection λ	660 nm
Detection Range	0.01 - 1.0 EU/mL	Endotoxin Std	E. coli O111:B4
Dilution Vol	2.0 mL	Matrix	LAL Reagent Water

QUANTITATIVE RESULTS

Parameter	Result
Endotoxin Level	< 0.20 EU/mL
Acceptance Limit	≤ 0.5 EU/mL
Sample CV (%)	N/A
Spike CV (%)	N/A
Spike Recovery (%)	N/A
Final Determination	PASS

CONTROLS

Control	Expected	Observed	Status
Positive Control	Detectable	As expected	Pass
Negative Control	No signal	As expected	Pass

INTERPRETATION

Endotoxin content was quantitatively determined using a kinetic chromogenic LAL assay in accordance with USP <85>. Result reported as below quantitation threshold. The measured endotoxin level meets the specified acceptance criteria. The sample passes the endotoxin limit test.

AUTHORIZATION

REVIEWED BY
Lemar Arghandiwal
Lab Director

